

REMARKS

Claims 1-4, 6-9, 19, 21-27, 29, 32, 34-40, 42-46, 48-52 and 56-60 were examined. Applicant notes with appreciation that claims 19, 21-24, 32, 34-37 and 42 are allowed. Claims 1-4, 6-9, 25-27, 29, 38-40, 42-46, 48-52 and 56-60 are rejected. Applicant amends claim 4, and asserts that no new matter is added herein. Amendment to claim 4 is supported by at least at claim 46 of the application. Applicant submits additional claims 61-66 for consideration and assert that no new matter is added therein. Specifically, claims 61 and 63 are supported at least at paragraphs 35 and 29 of the application; claims 62 and 64 are supported at least at paragraph 29 of the application; and additional claims 65-66 are supported at least by Figure 200 of Figure 1A and block 360 of Figure 2 of the application as filed. Applicant respectfully request reconsideration of claims 1-4, 6-9, 25-27, 29, 38-40, 42-46, 48-52 and 56-60, as amended, and consideration of claims 61-66 in view of at least the following remarks.

I. Claims Rejected Under 35 U.S.C. § 101

The Patent Office rejects claims 4 and 6-9 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Applicant amends claim 4 to require a fourth component to at least one of save an adjustment to the treatment plan, and execute the adjusted treatment plan. Hence, Applicants assert that claims 4 and 6-9 are directed to statutory subject matter. Thus, Applicants respectfully request the Patent Office withdraw the rejection above.

II. Claim Rejections Under 35 U.S.C §102

The Patent Office rejects claims 4 and 46 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0005027 to Nafstadius. (Nafstadius). It is axiomatic that to be anticipated every limitation of a claim must disclosed in a single reference.

Applicant respectfully disagrees with the rejection above and submit that claims 4 and 46 are not disclosed by Nafstadius for at least the reason that Nafstadius does not disclose a system comprising a treatment planning component, a simulation component, a third component, and a fourth component as required by claim 4 (paragraph 48). Figure 1 of Nafstadius describes "a radiation therapy process" which describes that "the first step in a radiation therapy process is diagnosis" (paragraph 49). Specifically, Nafstadius describes that there "different diagnostic machines" (see paragraph 50), a radiation therapy machine (see paragraph 51), and optionally a treatment simulation that is performed "before the actual radiation therapy treatment" (see paragraph 51).

However, the Patent Office does not identify and Applicant is unable to find any description in Nafstadius of a system (e.g., an apparatus comprising various components) comprising the components identified above for claim 4. Hence, Applicant respectfully requests the Patent Office withdraw the rejection above.

Similarly, independent claim 46 requires a system comprising a means for generating a treatment plan, a means for simulating the treatment plan, means for adjusting the treatment plan, and at least one means for saving the adjusted treatment plan or executing the adjusted treatment plan. An argument analogous to the one above for claim 4 applies here as well. Hence, Applicant respectfully requests the Patent Office withdraw the rejection above of claim 46.

The Patent Office rejects claims 56 and 60 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0048868 to Bailey, et al. (Bailey).

Applicant respectfully disagrees with the rejection above and submits that independent claim 56 is patentable over the cited references for at least the reason that Bailey does not disclose a system that comprises a simulation component "wherein said radiation source is at a fixed position relative to the gantry that simulates a distance between a patient and a treatment source in a treatment machine," as required by claim 56. As described in the present specification, at paragraphs 56 and 57, for example, prior art simulation systems required a source that could move in relation to the gantry

in order to simulate the distance to a patient that could be achieved on a treatment machine.

Bailey discloses positioning patient 62 on table 60, comparing CT scanner slices of the patient with images taken during the planning stage (e.g., of an original plan), and moving the table to insure that the target region of the patient is within the region of interest (e.g., as specified by an original plan) so that it can be exposed to the radiotherapy beam 50 (see paragraphs 48-49). Bailey also discloses adjusting the size and shape of the radiotherapy beam, adjusting the table position, and adjusting the angular position of radiation source 40 (to be according to the original plan), automatically, with some or complete control by the therapist, by using a computerized system including computer 80 (see paragraphs 51-53). Moreover, Bailey discloses a suitable collimator subsystem at 46 so that the cross-sectional shape and size of the radiotherapy beam can be modified to have a shape and size as specified by an original plan (see paragraph 41). For example, Bailey does not teach or suggest a system with a simulation component wherein the radiation source is at a fixed position relative to the gantry that simulates a distance between a patient and a treatment source in a treatment machine.

In the Response to Arguments section on page 14, number 29 of the current Office Action, the Patent Office asserts that the claim 56 limitation that the radiation source is at a fixed position relative to the gantry "that simulates a distance between a patient and a treatment source and a treatment machine" describes a manner in which the claimed apparatus is intended to be employed. Applicant disagrees as the above-noted limitation clearly requires that the fixed position relative to the gantry simulates a distance between a patient and a treatment source. Thus, this limitation positively recites and requires that the fixed position relative to the gantry creates a distance equal to a distance between a patient and a treatment source and a treatment machine (see MPEP section 2111.04). Hence, Applicant respectfully requests that the Patent Office withdraw the rejection above.

Also, Applicant respectfully disagrees with the rejection above and submits that independent claim 60 is patentable over the cited references for at least the reason that

Bailey does not disclose a distance from the radiation source to the axis of rotation is a fixed distance that simulates a treatment source to treatment system axis of rotation of linear accelerator treatment system, as required by claim 60. As described in the present specification, at paragraphs 56 and 57, for example, prior art simulation systems require a source that could be moved to change the distance between the source and the axis of rotation of the gantry, in order to allow the source to be at a distance that simulates a treatment source to treatment system axis of rotation of a linear accelerator treatment system. For example, Bailey does not teach or suggest a simulation system with a simulation component wherein the radiation source is at a fixed distance relative to the axis of rotation of the gantry that simulates a treatment source to treatment system axis of rotation of a linear accelerator treatment system.

Again, in the Response to Arguments section on page 14, number 29 of the current Office Action, the Patent Office asserts that the claim 60 limitation that the radiation source is at a fixed position relative to the gantry "that simulates a distance between a patient and a treatment source and a treatment machine" describes a manner in which the claimed apparatus is intended to be employed. Applicant disagrees as the above-noted limitation clearly requires that the fixed position relative to the gantry simulates a distance between a patient and a treatment source. Thus, this limitation positively recites and requires that the fixed position relative to the gantry creates a distance equal to a distance between a patient and a treatment source and a treatment machine. Hence, Applicant respectfully requests the Patent Office withdraw the rejection above.

The Patent Office rejects claim 57 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,301,325 to Besson et al. (Besson).

Applicant respectfully disagrees with the rejection above and submits that independent claim 57 is patentable over the cited references for at least the reason that Besson does not disclose means to move the patient support closer to and/or further from the gantry head as the gantry rotates to maintain a constant distance between the radiation source and a point defined in relation to the patient support, as required by amended claim 57. As described in the present specification, at paragraphs 56 and 57,

software may automatically move the treatment couch closer to the gantry head and, as the gantry head is rotated around the patient, the couch may be and automatically repositioned closer to and/or further from the gantry head to maintain this treatment distance. For example at paragraph 57, the present invention allows for maintaining a constant distance between the source, and e.g. a target, during rotation, with the capability to provide more accurate treatment simulation for machines having different source to isocenter distances.

On the other hand, Besson teaches that table 46 is moved along a translation axis 48 aligned with the Z-axis of the Cartesian Coordinate System (see column 5 lines 14-16), but does not teach moving the table closer to and/or further from the gantry head as the gantry rotates to maintain a constant distance between the radiation source and a point defined in relation to the patient support. Specifically, as shown in Figure 2 of Besson, the Z-axis extends in a direction between the patient's head and foot, but does not disclose moving the table closer to and/or further from the gantry head, as required by claim 57.

In the Response to Arguments section of the current Office Action, the Patent Office asserts that because Besson describes the patient support moving along the Z-axis, that the support moves closer to and/or further from the gantry head while the gantry rotates. However, as clearly defined in Fig. 1 and the description thereof, and as noted above, the Z-axis is orthogonal to (at a right-angle to) beam axis 41 and gantry plane 38 defining the x-y plane of a Cartesian coordinate system (see col. 5, lines 4-11 and Fig. 1). Thus, movement of the patient support along the Z-axis is not movement closer to and/or further from the gantry head while the gantry rotates.

Hence, for at least this reason, Applicant respectfully requests that the Patent Office withdraw the rejection above of claim 57.

Any dependent claims not mentioned above are submitted as not being anticipated or obvious, for at least the same reasons given above in support of their base claims in addition to further non-obvious limitations added by each dependent claim.

III. Claim Rejections Under 35 U.S.C §103

The Patent Office rejects claims 1, 2, 25, 29, 38, 40, and 42-44 under 35 U.S.C. §103(a) as being unpatentable over Chou et al. in view of Bailey et al.

Applicant respectfully disagrees with the rejection above for claims 1 and 43 for at least the reason that the cited references do not disclose adjusting automatically the treatment plan based on movement in a video display of the digital fluoroscopic image, as required by claims 1 and 43.

Chou describes a radiation therapy machine (see Abstract and col. 3, lines 35-38) having a video camera to record images on fluoroscopic plate 24 (see col. 3, lines 46-55). The captured analog television video images (see col. 4, lines 14-17) may each be converted to digital images and digitally processed for image enhancement (see col. 5, lines 7-11). Thus, each treatment image from camera 25 may be compared with a prior x-ray film by being superimposed on or presented side-by-side on display monitor 38 (see col. 5, lines 2-17). Specifically, the radiographic film image can thus be aligned with the therapy image for superimposed comparison (see col. 5, lines 25-27).

However, the Patent Office has not identified and Applicant is unable to find any teaching in Chou of adjusting a treatment plan based on movement in a video display of the digital fluorographic image as required by claims 1 and 43.

Moreover, Applicant asserts that Chou does not enable the above noted limitation. Chou simply mentions that "the stored sequences of images provide feedback for revisions of treatment planning, and quality assurance, and also provide a patient image file which is easily stored and retrieved i.e., for patient history purposes" (emphasis added) (see col. 5, lines 34-38). Hence, for at least this second reason, Applicant respectfully requests the Patent Office withdraw the rejection above.

Moreover, by adjusting automatically the treatment plan based on movement in a video as claimed, embodiments described in the specification of the present application, for example, without limitation thereto, provide benefits of allowing a real time digital video display (see paragraph 29 of the application) to display two dimensional, three dimensional, and four dimensional information and images (see paragraph 32 of the specification) of movement of a patient's internal anatomy (see

paragraph 35 of the specification) to automatically adjust a treatment plan (see paragraph 40 of the specification) such as using respiratory gating software based on the patient's external breathing pattern and range of motion to modify the plan to adjust for the breathing motion (see paragraph 41 of the specification). However, the cited references do not provide any of the benefits noted above.

Applicant also disagrees with the rejection of claims 25 and 38 for at least the reason that the cited references do not teach displaying a digital image of a patient based on the treatment plan, wherein the digital image is generated on a treatment simulator machine, as required by claims 25 and 38. As noted above, Chou describes a process performed only on a radiation therapy machine (see Abstract, Fig. 1, col. 3, lines 32-38). For example, the principal operation of Chou is that the video camera 50 is protected from the powerful therapy x-ray radiation within box 20 and only images fluoroscopic plate 24 (see col. 3, lines 46-51). Thus, the therapy machine receives a simulator radiograph 48, i.e., x-ray film, which is placed on light table 46 and its image is picked up by video camera 50 and brought to processor 42, where the image is digitized by the treatment machine and stored for comparison with a digitized image from camera 50 (see col. 5, lines 2-17).

Hence, the above noted limitations of claims 25 and 38 are not taught by the cited references. Thus, Applicant respectfully requests the Patent Office withdraw the rejection above of claims 25 and 38.

Claims 3 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. and Bailey et al. as applied to claims 1 and 43 above, and further in view of Weinberger et al. (US 5,764,723).

Weinberger teaches a radiation therapy apparatus and method for applying radiation to a patient in synchronism with one of a plurality of states of a cardiac cycle of the patient and one of a plurality of states of a respiratory cycle of the patient (see Abstract). However, Weinberger fails to cure the deficiencies of Chou and Bailey noted above for independent claims 1 and 43 from which claims 3 and 45 depend. Hence, Applicant respectfully requests the rejection above be withdrawn.

Claims 6, 8, 48, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nafstadius as applied to claims 4 and 46 above, and further in view of Miller et al. (US 5,117,829).

Miller describes at least one digitally reconstructed radiograph (DRR) generated from a CT scan data (see col. 3, lines 57-66). However, Miller fails to cure the deficiencies noted above for Nafstadius with respect to claims 4 and 46 from which claims 6, 8, 48 and 50 depend. Hence, Applicant respectfully requests the rejection above be withdrawn.

Claims 7 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nafstadius and Miller et al. as applied to claims 6 and 48 above, and further in view of Murphy et al. (US 5,901,199) and Jaffray et al. (US 2003/0007601).

Murphy teaches generating fluoroscopy images of a target volume (see Abstract). Also, Jaffray describes comparing images produced by a cone beam computerized tomography system 300 and images produced by a conventional scanner to determine whether system 300 provides images comparable in quality in terms of spatial resolution and contrast sensitivity (see paragraph 91). Thus, this comparison is related to development of system 300 but is not a practical application such as a comparison used during an adjustment of a treatment plan as required by claims 7 and 49. Consequently, neither Murphy nor Jaffray cure the deficiencies noted above for Nafstadius and Miller with respect to claims 6 and 48 noted above. Hence, Applicant respectfully requests the rejection above be withdrawn.

Claims 9 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nafstadius and Miller et al. as applied to claims 6 and 48 above, and further in view of Frohlich et al. (US 6,516,046).

Frohlich describes positioning a patient for radiotherapy or radio surgery on a linear accelerator using an x-ray image of a patient and a reconstructed image from a three-dimensional set of patient scanning data (e.g., a DRR) (see Abstract and col. 5, lines 34-36). However, the Patent Office has not identified and Applicant is unable to find any teaching in Frohlich of a cone beam scanner. Hence, Frohlich fails to cure the deficiencies noted above for Nafstadius and Miller with respect to claims 6 and 48 from

which claims 9 and 51 depend. Thus, Applicant respectfully requests the Patent Office withdraw the rejection above.

Claims 26, 27, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou et al. and Bailey et al. as applied to claims 25 and 38 above, and further in view of Frohlich et al..

Frohlich describes superimposing an x-ray image and a reconstructed radiograph (see col. 3, lines 19-24). However, Frohlich fails to cure the deficiencies of Chou and Baily noted above for claims 25 and 38 from which claims 26-27 and 39 depend. Hence, Applicant respectfully requests the Patent Office withdraw the rejection above.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton (2002/0193677) in view of Ivan et al. (US 6,031,888).

Applicant respectfully disagrees with the rejection above and submits that independent claim 52, as amended, is patentable over the cited references because the references do not teach or suggest performing brachytherapy comprising producing a treatment plan for placement of a radiation source in the patient based on the image of a patient produced using a flat panel imager while the patient is on the patient support; and treating the patient according to the treatment plan on the patient support, as required by amended claim 52.

The claim must be considered as a whole.

Ivan describes a CT scanner or an MRI device including CT x-ray amorphous silicon flat panel radiation detector 36 (see Abstract).

On the other hand, Thornton describes using ultrasound images formed in vertical slices through prostate 20 to implant brachytherapy seeds 40 (see Fig. 1, paragraphs 22 and 24). Moreover, the principle of operation of Thornton is to use ultrasound and fluoroscopy imaging but not requiring computed tomography (CT) imaging so that Thornton can be practiced in a wider variety of settings than is possible in the prior art (e.g., the invention may be practiced in an operating room and there is no need for a radiotherapy simulator couch or other specialized equipment) (see

paragraphs 55 and 56). Hence, Thornton teaches against using CT imaging and cannot be properly combined with Ivan.

Thus, Applicant respectfully requests the Patent Office withdraw the rejection above.

The Patent Office rejects claims 58 and 59 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,535,574 to Collins et al. (Collins), in view of Toshiba “Clinical Performance: Delivering upon the Promise of Multi-slice CT through Proven Performance”.

Applicant disagrees with the rejection above and submits that independent claim 58, is patentable over the cited references because the cited references do not teach or suggest a gantry that “comprises a single cast frame, wherein the frame comprises a first elongated portion and a second elongated portion disposed at an angle to one another,” as required by claim 58.

Collins describes a patient positioning system employing surface photogrammetry and portal imaging (see Title) including gantry 210 (see Fig. 1, column 3 lines 41-56). However, the Patent Office has not identified and Applicant is unable to find any teaching or suggestion in Collins that gantry 210 is a single cast frame gantry having two portions at an angle, as required by claim 58.

The Patent Office relies upon Toshiba to teach casting (page 3, col. 1, lines 28-31) and cites “to reduce vibrations (page 3, col. 1) as implied from Toshiba” as a motive to combine Collins with Toshiba. However, this motive is improper for two reasons.

First, the motivation is improper because Toshiba teaches overcoming vibration with a proprietary design that “uses supports at both ends of the tube housing to stabilize the anode” (see page 3, col. 1, lines 31-34). For instance, the gantry of Toshiba has a “unique tube design” (see page 3 column 1, lines 30-31) and triangular wedge shaped supports (see the picture on page 7 of the donut shaped gantry supported by wedges). Thus, a practitioner would not be motivated to use the Toshiba design to reduce vibrations in Collins because the principle of operation of the Toshiba vibration reduction design requires using supports and a tube housing which can not be properly combined with gantry 210 of Collins.

Second, Applicant asserts that the motivation of combining Collins with Toshiba to “reduce vibrations (page 3, col. 1) as implied from Toshiba,” is improper because the gantry of Collins does not experience the vibrations of concern in Toshiba since the gantry of Collins is not a ring or donut gantry, like the gantry of Toshiba. For example, for Toshiba, vibration may be an issue because ring or donut type gantries rotate much faster than the “L” type gantry of Collins. For instance, as known in the art, a ring or donut type gantry may rotate on the order of one to three times per second, while the “L” typed gantry in Collins may rotate at about one RPM (e.g., approximately 60-180 times slower than the gantry in Toshiba). Thus, a practitioner would not be motivated to look at or follow the teachings of Toshiba in order to reduce excessive vibration in the gantry of Collins, because as known in the art, they have different vibrational/resonance characteristics and such excessive vibration is not an issue for Collins.

In the Response to Arguments section on page 16, item 32 of the current Office Action, the Patent Office asserts that because Toshiba teaches using “a rigid, aluminum die cast gantry” for overcoming vibration issues it implies multiple motivations for having cast gantries. Applicant disagrees. A practitioner would not be motivated to attempt to use the single specific embodiment taught in Toshiba for other widely divergent gantry designs. The rigid, aluminum die cast gantry proprietary design of Toshiba requires supports at both ends of a tube housing to stabilize the anode (page 3, col. 1 and Fig. on page 7). Thus, there is no teaching or motivation in Toshiba that would cause a practitioner to believe that using a rigid, aluminum die cast gantry for a widely divergent design, such as the gantry claimed, would reduce excessive vibration. For example, there is no motivation to cause a practitioner to believe that such an application would reduce the resonance vibration of the claimed gantry.

Hence, for at least these reasons, Applicant respectfully requests the Patent Office withdraw the rejection above of claim 58.

Any dependent claims not mentioned above are submitted as not being anticipated or obvious, for at least the same reasons given above in support of their base claims in addition to further non-obvious limitations added by each dependent claim.

Thus, Applicant respectfully requests the Patent Office withdraw all of the rejections above.

V. Allowable Subject Matter

Applicant notes with appreciation that claims 19, 21-24, 32, 34-37 and 42 are allowed and the Reasons for Allowance therefore.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance, and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17.

If a telephone interview would expedite the prosecution of this Application, the Examiner is invited to contact the undersigned at (310) 207-3800.

Respectfully submitted,

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Lori Ciccio

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